Supreme Court, U.S.
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No. ____

# In The
# Supreme Court of the United States

GENENDO PHARMACEUTICAL, N.V.,
a Netherlands Antilles corporation,
*Petitioner*,

v.

UNITED STATES OF AMERICA,
*Respondent*.

*On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit*

## PETITION FOR WRIT OF CERTIORARI

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## QUESTIONS PRESENTED FOR REVIEW

(1) Whether the Court of Appeals for the Seventh Circuit ("Seventh Circuit") erred when, in contrast to a majority of other Courts of Appeal, it failed to consider dispositive legislative history in the first stage of its *Chevron* analysis and, therefore, improperly deferred to the interpretation of the Food and Drug Administration ("FDA") that the term "any" in 21 U.S.C. § 353(a) meant "some" rather than "all".

(2) Whether the Seventh Circuit failed to apply this Court's holding in *Massachusetts v. EPA*, 549 U.S. ___, 127 S. Ct. 1438 (2007), that the term "any" means "all" in a comparable statutory context.

## PARTIES TO THE PROCEEDING

The parties to this proceeding are:

GENENDO PHARMACEUTICAL, N.V., a Netherlands Antilles corporation; and

UNITED STATES OF AMERICA

## CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, Petitioner states as follows:

Genendo Pharmaceutical, N.V. is a privately held corporation. There are no publicly held companies that own 10% or more of Genendo Pharmaceutical, N.V.

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## OPINIONS BELOW

The opinion of the United States Court of Appeals for the Seventh Circuit is reported at 485 F.3d 958 and is reprinted in the Appendix to the Petition (App. 3a-16a). The District Court's Opinion is reported at 384 F. Supp. 2d 1205 and is reprinted in the Appendix to the Petition (App. 17a-50a).

## JURISDICTION

On May 10, 2007 the Seventh Circuit denied Genendo Pharmaceutical, N.V.'s ("Genendo") appeal of the District Court's decision. On July 10, 2007 the Seventh Circuit denied Genendo's petition for rehearing *in banc* and rehearing by the panel.

Review in this court is appropriate pursuant to 28 U.S.C. § 1254(1) for the review of final decisions of the United States Courts of Appeal pursuant to a petition for writ of *certiorari*.

## STATUTE AND REGULATION INVOLVED

21 U.S.C. § 353(a) which states in pertinent part:

> Regulations for goods to be processed, labeled, or repacked elsewhere. The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on

> condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

and 21 C.F.R. § 201.150 which states:

> (a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a drug which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501(b) and 502 (b), (d), (e), (f), and (g) of the act if:
>
> (1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug is to be processed, labeled, or repacked; or
>
> (2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug in such establishment as

will insure, if such specifications are followed, that such drug will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until 2 years after the final shipment or delivery of such drug from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

## STATEMENT OF THE CASE

### I. District Court Jurisdiction

The United States District Court for the Northern District of Illinois had jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1345, and under sections 332 and 334 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "FDCA" or "Act").

### II. Factual Background

The parties stipulated to the facts, including that the government did not contend that the at issue drugs were adulterated or counterfeit.

Genendo, as a regular part of its business, itself or through affiliates, purchases, trades, and sells pharmaceuticals manufactured overseas. (App. 24a, ¶ 17). 21 U.S.C. § 353(a) specifically permits and contemplates the repackaging and labeling of drugs "at establishments other than those where originally processed or packed . . . ."

At all relevant times, Phil & Kathy's was an Illinois FDA registered and inspected entity repacking and labeling drug products under the Act and regulations. (App. 35a, ¶¶ 106, 107). As required by 21 C.F.R. § 201.150, Genendo had a written agreement with Phil & Kathy's regarding the repackaging and labeling of prescription drugs ("201.150 Agreement"). (App. 31a, ¶¶ 75, 77).

In September and October 2003 letters, Genendo advised the government that it intended to import Lipitor into the United States. (App.25a, ¶¶ 29, 31). In the October 24, 2003 letter, Genendo advised the United States that it intended to import Lipitor pursuant to a September 17, 2003 invoice to Phil & Kathy's to be repackaged and labeled *before* distribution and dispensing to consumers and others. (App. 25a, ¶ 31). Genendo then imported the Lipitor. (App. 25a, ¶ 30). On or about December 16, 2003, based on the information provided by Genendo, the government seized the Lipitor (n/k/a the "Seized Lipitor") at customs. (App. 26a, ¶ 32).

Pfizer, Inc. ("Pfizer") manufactures Lipitor. (App. 26a, ¶35). Pfizer submitted a New Drug Application ("NDA") for Lipitor to the FDA. The FDA approved the NDA for Lipitor. (App. 26a, ¶¶ 36-38). A Pfizer facility in Loughbeg, Ireland, is identified in the FDA-approved NDA as a manufacturing facility for Lipitor intended for sale and distribution in the United States, including 10 mg. and 20 mg. dosages. (App. 26a, ¶ 39). The FDA inspects the Pfizer Loughbeg, Ireland facility. (App. 26a, ¶ 40). The Seized Lipitor was manufactured (*i.e.*, formed into the solid oral dosage

form) by Pfizer in the Loughbeg, Ireland facility listed on the NDA. (App. 32a, ¶ 81).

The Seized Lipitor is packaged in blister packs. (App. 32a, ¶ 84). The FDA approved NDA for Lipitor includes blister packs for the 10 mg. and 20 mg. dosages. (App. 26a, ¶ 39).

The expiration period in the FDA-approved NDA for blister packed Lipitor is two years from date of manufacture. (App. 27a, ¶ 42). On December 16, 2003, the date of the seizure, the expiration period for the Seized Lipitor had not run. (App. 29a, ¶ 57). The two lots of the Seized Lipitor were manufactured on January 16, 2003 and February 18, 2003. (App. 29a, ¶ 58). Therefore, when seized, 13 months remained on one lot and 14 months on the other.

Genendo purchased the Seized Lipitor in Brazil (App. 27a, ¶ 43) and imported it into the United States (App. 27a, ¶ 44). The labeling on the Seized Lipitor is in Portuguese; specifically, each blister sheet of ten tablets and each 30-tablet box are labeled in Portuguese. (App. 28a, ¶ 50). The labeling approved at the time of seizure for the Seized Lipitor for sale in the United States is publicly available on the FDA website.[1] The government does not claim the Seized Lipitor is adulterated or counterfeit. (App. 33a, ¶ 93).

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[1] *See* http://www.accessdata.fda.gov/scrips/cder/drugsatfda/index.cfm?fuseaction =search.label_approvedhistory.

## III. Lower Court Proceedings

On November 14, 2003, the Government filed an Amended Verified Complaint for Injunctive Relief in the United States District Court for the Northern District of Illinois naming Genendo as a defendant. On December 16, 2003, pursuant to a warrant issued following the filing of the Amended Verified Complaint, the government seized the Seized Lipitor. The government alleged the Seized Lipitor was misbranded and an unapproved new drug. After a one day trial, the District Court decided, on the basis of the stipulated facts, that the Seized Lipitor was an unapproved new drug that violated 21 U.S.C. § 355.

Despite the fact that the government never contended that the Seized Lipitor was either adulterated or counterfeit, the District Court concluded the exemption contained in 21 U.S.C. § 353(a)

> exempting from any labeling or packaging requirement of [the FDCA] drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment

did not apply to the Seized Lipitor because the "labeling and packaging requirements" referred to in

§ 353(a) applied only to general "labeling and packaging" but not the requirements for packaging set forth in the approved NDA, a part of the FDCA referred to in § 353(a). The District Court granted the government's request for condemnation of the drugs and injunctive relief.

The Seventh Circuit affirmed the decision of the District Court using different reasoning. The Seventh Circuit determined that the use of the term "any" in § 353(a) was ambiguous and, therefore, the Food and Drug Administration's ("FDA") interpretation that the term "any" meant some but not all of the labeling and packaging requirements of the Act would be afforded *Chevron* deference.[2] Despite being presented the legislative history of Section 353(a) in Genendo's opening brief, reply brief, and motion for rehearing *in banc,* the Seventh Circuit did not consider the legislative history that demonstrated specific Congressional intent that "any" in § 353(a) meant "all." Had it done so, Genendo would have prevailed because the statements of the sponsor of the FDCA, made during floor debate, make clear Congress's intent that "any" mean "all."[3]

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[2] *Chevron* deference refers to *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837.

[3] This court decided *Massachusetts v. EPA*, 549 U.S. ___, 127 S. Ct. 1438 (2007) after the Seventh Circuit heard oral argument on Genendo's appeal. Therefore, pursuant to Fed. R. App. Proc. 28(j), Genendo provided the Seventh Circuit with a copy of *Massachusetts v. EPA*. *Genendo*, 485 Fd at 963 n.3.

Genendo filed a motion for rehearing *in banc* which the Seventh Circuit denied.

## REASONS FOR GRANTING THE PETITION

This Court should grant the petition for writ of *certiorari* because:

1. Pursuant to Sup. Ct. Rule 10(a), a Split of Authority Exists Among the Circuits Concerning Whether Legislative History Should Be Used In Stage I or Stage II of a *Chevron* Analysis; and

2. Pursuant to Sup. Ct. Rule 10(c), the Seventh Circuit Decided an Important Federal Question Which Conflicts With This Court's 2007 Decision in *Massachusetts v. EPA* Regarding the Meaning of the Adjective "any" in Comparable Statutory Language.

### I. Pursuant to Sup. Ct. Rule 10(a), a Split of Authority Exists Among the Circuits Concerning Whether Legislative History Should Be Used In Stage I or Stage II of a *Chevron* Analysis.

The sole issue on appeal, as articulated by the Seventh Circuit, was "whether the seized Lipitor is an unapproved "new drug." *United States v. Genendo Pharm., N.V.*, 485 F.3d 958, 962 (7th Cir. 2007). The Seventh Circuit went on to state that the only relevant question in making that determination was whether 21 U.S.C. § 353(a) exempted the Seized Lipitor from

the labeling and packaging requirements of the Act. *Genendo*, 485 F.3d at 962.

21 U.S.C. § 353(a) states:

> The Secretary is *directed* to promulgate regulations exempting from *any* labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(emphasis added).

The Seventh Circuit's determination whether the Seized Lipitor was exempt from the labeling and packaging requirements of the Act turned on whether the word "any," as used in § 353(a) meant "all," as Genendo contended, or "some," as the government contended. *Genendo*, 485 F.3d at 963. In order to decide the meaning of "any," the Seventh Circuit decided that it must first determine "the level of deference to be accorded to the FDA's interpretation of Section 353(a)." *Genendo*, 485 F.3d at 962. In so doing, it engaged in a flawed, *i.e.*, incomplete, *Chevron* analysis by ignoring the legislative history.

Under *Chevron*, a court must first determine whether "Congress has directly spoken to the precise

question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron* at 842-43. If a court determines that the statute is "silent or ambiguous" with respect to the specific issue, then the reviewing court engages in the second step of a *Chevron* analysis in determining whether the agency's "answer is based on a permissible construction of the statute." *Id.*[4]

The determination of whether Congress has spoken on the issue or whether the statute is ambiguous has a profound impact on the outcome of cases involving an agency's proposed interpretation of a statute.

> [Because] it is only when a court cannot discern an unmistakably clear expression of congressional intent that the *Chevron* inquiry moves into its second stage. Until then, deference is not a consideration - but from that point forward, deference looms large. The court must examine the agency's interpretation to see how it relates to the statute. This examination involves a high degree of respect for the agency's role. The agency need not write a rule that serves the statute in the best or most logical manner; it need only write a rule that flows rationally from a permissible construction

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[4] Genendo has always maintained the statute was clear on its face. Genendo presented the District Court and the Seventh Circuit with the legislative history of § 353(a) to establish that point.

> of the statute. *See, e.g., Cohen v. Brown Univ.*, 991 F.2d 888, 899 (1st Cir. 1993) (noting that it is unimportant to the *Chevron* analysis whether the court, if writing on a pristine page, would prescribe a different version of the regulation).

*Strickland v. Comm'r, Me. Dep't of Human Serv.*, 48 F.3d 12, 17 -18 (1st Cir. 1995).

Thus, if a court determines that the statute is unambiguous and the intent of Congress is clear, then the agency receives *no deference*, or, in other words, the statute is what it says. If a court determines that the statute is ambiguous, then an agency receives significant, but not absolute, deference in its interpretation of the statute.

The Seventh Circuit's mistaken determination that Congressional intent was ambiguous had a profound impact here. It resulted in Genendo's loss despite the fact that the floor debate remarks of the Senate sponsor of the FDCA concerning this section demonstrates "any" means "all."

There is a split among the circuits whether to use legislative history when conducting step one of a *Chevron* analysis. A majority of circuits have determined that in step one, courts "look first to whether the statute's language and legislative history clearly demonstrate what Congress intended." *Senger v. City of Aberdeen*, 466 F.3d 670, 672 (8th Cir. 2006). "When they do, that intent controls and a court will

not defer to any regulation that interprets the statute in a contrary manner." *Id.*[5]

In contrast, the Seventh Circuit has adopted the view that legislative history should never be considered in Stage I of a *Chevron* analysis. *United States v. Dierckman*, 201 F.3d 915, 923 n. 12 (7th Cir. 2000); *see also Square D Co. v. Comm'r*, 438 F.3d 739, 745 n. 4 (7th Cir. 2006); *Bankers Life & Cas. Co. v. United States*, 142 F.3d 973, 983 (7th Cir. 1998).[6] Consistent with this view, the Seventh Circuit completely ignored Congress's intent as revealed in the legislative history.

The First, Second, and Third Circuits have expressed their frustration over a lack of guidance from this Court on the role of legislative history in a *Chevron* analysis. Each of the First, Second, and Third Circuits, have urged this Court to clarify this issue.

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[5] *See Hackwell v. United States*, 491 F.3d 1229, 1233 (10th Cir. July 5, 2007); *Yi v. Fed. Bureau of Prisons*, 412 F.3d 526, 533 (4th Cir. 2005); *Shays v. FEC*, 414 F.3d 76, 84-85 (D.C. Cir. 2005); *Fullenkamp v. Veneman*, 383 F.3d 478, 484-85 (6th Cir. 2004); *Walton v. Rose Mobile Homes LLC*, 298 F.3d 470, 478 (5th Cir. 2002); *Davis v. S. Energy Homes, Inc.*, 305 F.3d 1268, 1278 (11th Cir. 2002).

[6] At one point, the Seventh Circuit did consider legislative history in Phase I of the *Chevron* analysis. *See, e.g., Illinois EPA v. United States EPA*, 947 F.2d 283, 289 (7th Cir. 1991).

The Second Circuit has stated that this Court "has issued mixed messages as to whether a court may consider legislative history at this stage of the analysis (step one of *Chevron*)." *Coke v. Long Island Care at Home, Ltd.*, 376 F.3d 118, 127 (2d Cir. 2004). The Second Circuit catalogued examples in which this Court differed in its use of legislative history in Phase I or Phase II of a *Chevron* analysis.

> Compare *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 137, 146 L. Ed. 2d 121, 120 S.Ct. 1291 (2000) (effectively considering legislative history at step one of Chevron analysis), *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 697-99, 115 L. Ed. 2d 604, 111 S.Ct. 2524 (1991) (same), *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 649-50, 110 L. Ed. 2d 579, 110 S.Ct. 2668 (1990) (same), and *Japan Whaling Ass'n v. Am. Cetacean Soc'y*, 478 U.S. 221, 233-41, 92 L. Ed. 2d 166, 106 S.Ct. 2860 (1986) (same), with *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 293 n.4, 100 L. Ed. 2d 313, 108 S.Ct. 1811 (1988) (opinion of Kennedy, J.) (noting in the first step of a *Chevron* inquiry that "any reference to legislative history [] is in the first instance irrelevant"), *Sutton v. United Air Lines, Inc.*, 527 U.S. 471, 482, 144 L. Ed. 2d 450, 119 S.Ct. 2139 (1999) (finding statutory text clear enough to ignore any arguments from legislative history), and *Nat'l R.R. Passenger Corp. v. Boston & Me. Corp.*, 503 U.S. 407, 417, 118 L. Ed. 2d 52, 112 S.Ct. 1394 (1992) (finding only statutory text to be relevant for first-step *Chevron* analysis).

*Coke*, 376 F.3d at 127 n.3 (2d Cir. 2004).

Similarly, the Third Circuit has stated:

> *It is not clear whether it is appropriate for us to consider legislative history* to determine whether a statute is unambiguous at this point in Chevron analysis. Compare *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 137, 120 S.Ct. 1291, 146 L. Ed. 2d 121 (2000) (considering legislative history at step one of Chevron analysis), with *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 293 n. 4, 108 S.Ct. 1811, 100 L. Ed. 2d 313 (1988) (stating that "any reference to legislative history . . . is in the first instance irrelevant" in step one of Chevron analysis) and *Nat'l R.R. Passenger Corp. v. Boston & Me. Corp.*, 503 U.S. 407, 417, 112 S.Ct. 1394, 118 L. Ed. 2d 52 (1992) (finding only statutory text is relevant for step one of Chevron analysis).

*Santiago v. GMAC Mortg. Group, Inc.*, 417 F.3d 384, 388 n.3 (3d Cir. 2005) (emphasis added).

The First Circuit has also recognized the different views of this Court, among others, on the appropriate use of legislative history.

> In performing the first part of a *Chevron* analysis, no deference is due. Instead, courts must look primarily to the plain meaning of the statute, drawing its essence from the "particular statutory language at issue, as well as the language and design of the statute as a whole." *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291,

108 S.Ct. 1811, 1818, 100 L.Ed.2d 313 (1988); *accord Dunn v. Secretary of Agric.*, 921 F.2d 365, 366-367 (1st Cir. 1990). Beyond this point, *it remains unclear* whether, and if so, to what extent, a court engaged in the first stage of a *Chevron* inquiry may use other tools of statutory construction, such as legislative history, in searching for Congress' unambiguously expressed intent on a particular issue. See *Dunn*, 921 F.2d at 367 n.2 (citing conflicting cases but not resolving the point).

Legislative history is subject to many and varied criticisms, and the uncertainty about its value in general parallels the uncertainty about its value in relation to the *Chevron* doctrine. Respectable authority indicates that it is appropriate to employ all the "traditional tools of statutory construction" in the first part of the *Chevron* analysis when the statutory language itself is not dispositive. *See INS v. Cardoza-Fonseca*, 480 U.S. 421, 432-43, 446, 107 S.Ct. 1207, 1221, 94 L.Ed.2d 434 (1987) (examining legislative history to confirm the validity of an interpretation suggested by the statute's language) (dictum); *Massachusetts v. Lyng*, 893 F.2d 424, 429 (1st Cir. 1990). But there is also respectable support for the proposition that the *Chevron* analysis, in its initial phase, does not look beyond the statutory text. *See, e.g., National R.R. Passenger Corp. v. Boston & Me. Corp.*, 503 U.S. 407, 416-17, 112 S.Ct. 1394, 1401, 118 L.Ed.2d 52 (1992) (stating that deference is due so long as "the agency interpretation is not in conflict with the plain

> language of the statute"); *K Mart Corp.*, 486 U.S. at 292, 108 S.Ct. at 1818 ("If the agency regulation is not in conflict with the plain language of the statute, a reviewing court must give deference to the agency's interpretation of the statute."); *NLRB v. United Food & Commercial Workers Union*, 484 U.S. 112, 133-34, 108 S.Ct. 413, 426-27, 98 L.Ed.2d 429 (1987) (Scalia, J., concurring) (criticizing dictum in *Cardoza-Fonseca*); *Stowell v. Secretary of HHS*, 3 F.3d 539, 543 (1st Cir. 1993) (approving deference where "statute is silent with respect to a specific question").

*Strickland*, 48 F.3d at 16-17 (footnote omitted) (emphasis added).

This Court has engaged in an ongoing debate about the use of legislative history in statutory construction cases. *See, e.g., Babbit v. Sweet Home Chapter of Cmtys. for a Great Or.*, 515 U.S. 687, 704-05 (relying on legislative history) and *Sweet Home*, 515 U.S. at 726-27 (1995) (Scalia dissenting); *City of Chicago v. Env. Def. Fund*, 511 U.S. 328, 337 (1994) (refusing to use legislative history to help interpret statute), and *City of Chicago*, 511 U.S. at 345 n.7 (Stevens dissenting) (relying on legislative history).

Whether a court should use legislative history in conducting its Phase I *Chevron* analysis is important. If the goal of *Chevron* analysis Phase I is to determine the intent of Congress, then reference to legislative history is vital. If a court does not use legislative history in Phase I, the court runs the risk, as

happened here, of ignoring Congress's directive and bestowing unwarranted deference on an agency.

In a law review article published while Chief Judge of the First Circuit, Justice Breyer argued in favor of the importance of legislative history in interpreting statutes. In discussing the use of legislative history to help determine the appropriate interpretation of changes to the Bankruptcy Code in *In re Arnold Print Works, Inc.*, 815 F.2d 165 (1st Cir. 1987), Justice Breyer stated:

> Without the legislative history, without the floor statements, we might have reached a different result. After all, state-law contract claims, whether pre- or post-petition, look very much alike, and both sorts of claims are only peripherally related to bankruptcy itself. But the result suggested by any such "purpose-free" analogy would be pointless and wrong, for it would not comport with the legislators' basic statutory objectives.
>
> More importantly, the incompatibility between the result we could have reached (but did not) and those congressional objectives, seen from a general institutional or governmental perspective, would be undesirable. The undesirability consists, not simply of the fact that Representatives Kastenmeier and Kindness were democratically elected, but also of the fact that the statute's general objectives (and the detailed provisions needed to implement the objectives) reflect far more than the work of the two Representatives themselves.

The objectives, and the detailed provisions, reflect the work of all the representatives of the bankruptcy community involved in the legislative process that produced the bankruptcy bill, namely bankruptcy judges, practitioners, teachers, and many others who worked on the details of the law. Their knowledge and experience, likely communicated through staff, with or without compromises, is embodied both in particular statutory phrases and in reports and floor statement language. To take from the courts the power to refer to legislative history in a case such as this one is to cut an essential channel for communications with these informed communities of groups and individuals, a channel that runs from those affected by a law's implementation, through courts and legislators, to those involved in the law's creation. To reach a result inconsistent with their work denies the public a significant part of the benefit of their expertise -- an important matter in so technical an area where the knowledge of informed groups is likely to produce a more workable, legally "better" statute. More significantly, reaching such an inconsistent result defeats the reasonable expectations of the many individuals and groups involved in the legislative process. As long as we believe that one important goal of a legal system is to maintain rules of law consistent with the reasonable expectations of those who live within it, this result is undesirable.

Stephen Breyer, *On The Uses of Legislative History in Interpreting Statutes*, 65 S. Cal. L. Rev. 855-56 (1991).

Much like the Bankruptcy Code, the FDCA was the result of compromise among interested parties. The very section at issue here was debated on the floor of the Senate, and Congress reached a satisfactory compromise. To disregard that history is to thwart the express will of Congress and the compromise Congress painstakingly reached.

Congress's careful weighing of the respective interests at issue, *i.e.*, assuring that it did not harm the "practice of the trade" of repackaging and labeling drugs while assuring drugs that enter consumer directed commerce are neither adulterated nor misbranded, can be seen in § 353(a). Section 353(a) never exempts adulterated drugs and only exempts drugs while en route to or held by a registered repackager/labeler. By refusing to consider the legislative history of § 353(a), the Seventh Circuit replaced Congress's careful assessment of the proper balance of those interests with the opinion of the FDA.

In § 353(a), Congress expressly contemplated that drugs *not* compliant with the NDA could travel to an FDA registered and inspected repackaging and labeling establishment. Moreover, the Congressional Record clearly demonstrated Congress's intent. In discussing Section 353(a), the Senate sponsor of the bill unequivocally stated the intent of Congress with regard to Section 353(a):

> Mr. COPELAND. Mr. President, if I did not feel that we have fully covered the suggestion made

by the senior Senator from New Jersey, so far I could do so, I would at once accept the amendment. The Senator has already mentioned subdivision (1), on page 22, and perhaps the Senator did not know that on line 3 we have stricken out the word "authorized" and have provided that the Secretary shall be directed. The Secretary is directed to promulgate regulations exempting from labeling such articles as those which the Senator has referred.

I am satisfied that with this change, which was suggested by the Senator from Michigan [Mr. Vandenberg], directing the Secretary to take such action, we are not leaving the matter to anybody. *The Secretary must do what the Senator seeks* to have done when the substances covered by the provision are shipped in large quantities are not sold to the consumer. *They need not be labeled, and so forth, until after they are ready actually to be sent to another to the ultimate consumer.* So I feel that under subsection (1) the industry in which the Senator is interested is fully protected, in view of the fact that *we have not given the Secretary any option in the matter, but he must perform this prescribed duty.*

Federal Food, Drug and Cosmetic Act, A Statement of its Legislative Record (hereinafter, "FDCA Leg. Rec."), 74th Cong. 363 (1938 *reprinted* 1987) (emphasis added).

The Seventh Circuit never considered this compelling legislative history in its *Chevron* analysis, let alone in Phase One. In so doing, the Seventh Circuit ignored the legislative history of the FDCA and ignored Congress's clearly expressed intent that drugs that meet the requirements of § 353(a) be exempt from *all* of the labeling and packaging requirements of the Act.

The Seventh Circuit also gave the FDA authority that Congress specifically denied it. That is, the Seventh Circuit granted the Secretary "options." Had Genendo shipped the Seized Lipitor to Washington, D.C. (D.C. Circuit), Baltimore (Fourth Circuit), New Orleans (Fifth Circuit), Cincinnati (Sixth Circuit), Denver (Tenth Circuit), or Atlanta (Eleventh Circuit) rather than Chicago (Seventh Circuit), the outcome in this case would have been different because all of these circuits would have considered the legislative history demonstrating Congress's intent that "any" means "all."

The Seventh Circuit's decision cannot be reconciled with Senator Copeland's instruction that the drugs "need not be labeled and so forth until after they are ready actually to be sent to the ultimate consumer." The decision eviscerated § 353(a) directing that the FDA exempt drugs that met the enumerated requirements of § 353(a) from all the labeling and packaging requirements of the Act.[7] If the drugs had

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[7] The Exemption is exceedingly narrow, applying only to packaging and labeling. The FDA argued that to give effect to the congressional directive contained in Section 353(a) to exempt

to comply with the NDA prior to processing, there would have been no reason for the exemption. It is, after all, an exemption, and if not from the labeling and packaging requirements of the NDA, then what?

Further proof is found in the fact that the section requires no label at all, and of course, any drug that is not labeled does not comply with the NDA, which speaks to the fact that Congress precisely envisioned all labeling and packaging (including any listed on the NDA) were not required until the drug was removed from the "processing, labeling, or repacking establishment." The Seventh Circuit's decision makes no sense given the legislative history. Had the Seventh Circuit considered the legislative history of the Act in Phase One of its *Chevron* analysis, there could not be any doubt or ambiguity regarding the definition of "any" in § 353(a) even without this Court's decision in *Massachusetts v. EPA*, 549 U.S. ___, 127 S.

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drugs that meet the requirements of Section 353(a) from any of the labeling and packaging requirements of the Act would eviscerate the new drug approval process. Nothing could be further from the truth. The requirements of the new drug approval process are extensive and are not limited to labeling and packaging. They include manufacturing processes, formulation, clinical trials, and substantial other requirements for a drug to be an "approved" new drug. See 21 U.S.C. § 355(b)(1). Thus, it is a complete distortion to claim that giving effect to Section 353(a) would eviscerate the new drug approval process. It would simply give effect to the plain statutory language as promulgated by Congress that drugs that meet the requirements of Section 353(a) are exempt from the "labeling and packaging" requirements of the Act and then only while en route to and held by the repackager.

Ct. 1438 (2007). Senator Copeland's statement clearly announces the intent of Congress that the Secretary was to promulgate regulations that exempted drugs that met the other requirements of § 353(a) from all of the labeling and packaging requirements of the Act.

This Court should grant the petition for writ of *certiorari* because it gives the Court the opportunity to clarify at what stage of the *Chevron* analysis it is appropriate to use legislative history; gives this Court an opportunity to end the circuit split and confusion on this issue; and gives this Court the opportunity to assure that courts will not inappropriately defer to agency positions without considering the intent of Congress as expressed in the legislative history and the statute. In this case, the Seventh Circuit recognized that Genendo's interpretation of 353(a) was entirely reasonable. *Genendo*, 485 F.3d at 963-964. However, because the Seventh Circuit did not consider the clear legislative history, it impermissably deferred to the interpretation of the FDA.

## II. Pursuant to Sup. Ct. Rule 10(c), the Seventh Circuit Decided an Important Federal Question Which Conflicts With This Court's 2007 Decision in Massachusetts v. EPA Regarding the Meaning of the Adjective "any" in Comparable Statutory Language.

As in *Massachusetts v. EPA*, 549 U.S. _____, 127 S. Ct. 1438 (2007), here too, "any" can only mean "all." In *Massachusetts*, this Court interpreted § 202(a)(1) of the Clean Air Act which provides that EPA "shall by regulation prescribe . . . standards applicable to the emission of *any* air pollutant of any class or classes of

new motor vehicles or new motor vehicle engines which in [the Administrator's] judgment cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare." *Massachusetts*, 549 U.S. at ___, 127 S. Ct. 1459-1460 (emphasis added) (internal citation omitted). The EPA refused, claiming it was not required to regulate substances that contribute to climate change because carbon dioxide is not an "air pollutant" within the meaning of the provisions. 549 U.S. at ___, 127 S. Ct. at 1459. However, this Court found "the definition embraces *all* airborne compounds of whatever stripe, and underscores that intent through the repeated use of the word 'any.'" *Massachusetts*, 549 U.S. at ___, 127 S. Ct. at 1460 (emphasis added). The Court held the statute unambiguous and, therefore, the EPA's interpretation was not entitled to *Chevron* deference.

The particular meaning of "any" and the effect it has on a phrase *are always* clear and unambiguous, irrespective of context or function. "Any" can act as an adverb, a pronoun, or an adjective. As an adverb, it always precedes an adjective or adverb and has the meaning "to any degree or extent" or "at all." "Any" as an adverb will be found in the following sentence: "Had this brief been *any* longer, I would not have filed it." As a pronoun, "any" denotes one or more not specifically defined people or things, as in: "All the presidential candidates said they would debate one another in Arlington, VA, but I doubt if <u>any</u> will actually show up."

"Any" can also serve as an adjective, its most common use. Depending on context, "any" when used as an adjective can mean "one," "some," "every," or

"all." The "any" that appears in § 353(a) functions as an adjective and when "any" functions as an adjective, it always precedes a noun (or noun phrase), "any money" or "any labeling or packaging requirement of this chapter...."

Grammatically, "any" in the context "exempting from any labeling or packaging requirement of this chapter" cannot mean one, some, or more, as the district court and the Seventh Circuit ruled. The "regulation" referenced in the section covers every and all labeling and packaging requirement(s) of the FDCA. The phrase cannot imply one, a limited number, or no labeling and packaging requirements. Under the Seventh Circuit's decision, it could, theoretically, mean "none," which would have gutted the explicit congressional direction contained in the section. As written, the statute exempts both every labeling and packaging requirement and all labeling and packaging requirements in the Act. If Congress had intended to limit the number of labeling and packaging requirements to not mean all requirements, but only one or several, Congress would have used the following hypothetical language or some variation thereof:

> The Secretary is given the authority to promulgate regulations that, *at the discretion* of the Secretary, *may* exempt from *certain* labeling or packaging requirements of this chapter drugs and devices which are....

This language is actually close to the language that Congress specifically amended away. 74th Cong. 363 (1938 *reprinted* 1987). Further unassailable support

is that the section's inclusion of "directed", coupled with "from any", eliminates any FDA discretion or grammatical confusion. If Congress had intended to confer discretion upon FDA, then Congress would have used "may" or not stricken the word "authorized." *Id.* Indeed, when FDA promulgated 21 C.F.R. § 201.150, it clearly knew what Congress directed by itself then incorporating "shall" into its regulation. It would be senseless for Congress to mandate an exemption and then allow the agency to promulgate regulations to not exempt. Of course Congress did not do that. As Senator Copeland stated "we have not given the Secretary any option in the matter, but he must perform this prescribed duty." FDCA Leg. Rec. at 363.

## CONCLUSION

This Court should grant the Petition for Writ of Certiorari because:

1. The Seventh Circuit erred when it failed to consider legislative history directly on point in Phase One of its *Chevron* analysis; and

2. It is impossible, after this Court's decision in *Massachusetts v. EPA*, for "any", as determined by the Seventh Circuit, to be "ambiguous."

Respectfully submitted,

GENENDO PHARMACEUTICAL N.V.

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# APPENDIX

## APPENDIX A

## UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

**No. 05-4608**

**[Filed July 10, 2007]**

| | |
|---|---|
| UNITED STATES OF AMERICA, Plaintiff-Appellee, | ) |
| v. | ) |
| GENENDO PHARMACEUTICAL N.V., a Netherlands Antilles Corporation, Defendant-Appellant. | ) |

Appeal from the United States District Court
for the Northern District of Illinois,
Eastern Division. No. 03 C 6495.
James F. Holderman, Chief Judge.

Before Honorable ILANA DIAMOND ROVNER, Circuit Judge, Honorable TERENCE T. EVANS, Circuit Judge, Honorable DIANE S. SYKES, Circuit Judge.

## ORDER

On consideration of the Petition for Rehearing en Banc and Rehearing by the Panel filed by Defendant-Appellant on June 25, 2007, no judge of the court having called for a vote and all of the judges on the original panel having voted to deny the Petition for Rehearing,

IT IS HEREBY ORDERED that the Petition for Rehearing en Banc and Rehearing by the Panel is DENIED.

## APPENDIX B

## UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

**No. 05-4608**

**[Filed May 10, 2007]**

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

GENENDO PHARMACEUTICAL, N.V.,
Defendant-Appellant.

Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.
No. 03 C 6495--James F. Holderman, Chief Judge.

Before ROVNER, EVANS, and SYKES, Circuit Judges.

### OPINION

ROVNER, *Circuit Judge*. This case involves Genendo Pharmaceutical's attempt to import prescription drugs intended for sale in other countries into the United States for repackaging and

distribution. Genendo maintains that the importation is authorized pursuant to certain statutory exemptions for drugs being repackaged within the United States. The district court disagreed, and granted the United States' motion for seizure and condemnation of the drugs, as well as a permanent injunction barring further importation.

## I.

Genendo, located in Curacao, Netherlands Antilles, purchases, trades, and sells pharmaceuticals. One portion of its business includes obtaining prescription drugs overseas and importing them into the United States for resale. Some of the drugs it imports were originally intended for sale outside of the United States. As relevant here, in September 2003, Genendo imported 60 boxes of prescription Lipitor containing 10 milligram tablets of Lipitor, and 48 boxes containing 20 milligram tablets of Lipitor.[1] Lipitor is manufactured by Pfizer, Incorporated and is used to treat high cholesterol. Genendo purchased the Lipitor in Brazil in order to import it into the United States.

Before importing the Lipitor, Genendo filed an action for a declaratory judgment that its importation of Lipitor was permissible under the Federal Food, Drug, and Cosmetic Act ("the FDCA"). 21 U.S.C. §§ 301-399. The United States successfully moved to dismiss the action on the grounds that there was not yet an agency action ripe for review. Several months

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[1] The action initially also involved 24,990 tablets of 40 milligram Zocor (another cholesterol-lowering drug).

later, Genendo imported, and the government seized, the Lipitor.

At issue is whether the seized Lipitor is an "unapproved new drug," *see* 21 U.S.C. § 355(a), because it does not comply in certain respects with the existing FDA-approved New Drug Application for Lipitor. The new drug approval process is one piece of the FDCA's comprehensive scheme regulating the manufacture, sale, and importation of prescription drugs. Before a drug is introduced into interstate commerce, a drug manufacturer must obtain FDA approval (specific to each drug and each manufacturer) of the manufacturing process, labeling, and packaging of the drug. 21 U.S.C. § 355(b)(1). The approval process addresses the drug's safety and effectiveness, *id.* § 355(b)(1)(A), its chemical composition, *id.* § 355(b)(1)(B), and how it is distributed--i.e., "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing" and the proposed labeling for the drug, *id.* §§ 355(b)(1)(D) & (F). Thus, before gaining FDA approval for Lipitor as a "new drug" under the FDCA, *see* 21 U.S.C. § 321(p), Pfizer submitted a New Drug Application ("NDA") which contains, among other things, detailed specifications regarding the drug's manufacture and packaging. *See* 21 U.S.C. § 355(a) (stating necessity of an approved new drug application).

As relevant here, the NDA for Lipitor specifies the following relating to its manufacture and packaging for sale in the United States: (1) the Lipitor must be manufactured at a Pfizer facility in Loughbeg, Ireland; (2) it must be packaged in either Frieburg, Germany or Vega Baja, Puerto Rico; (3) it must be packed in 100-

tablet boxes containing ten blister cards of ten tablets each; and (4) it must be labeled in English. Additionally, the NDA provides for a two-year expiration period for Lipitor distributed in the United States.

At the time the United States seized the Lipitor imported by Genendo, it deviated from the FDA-approved NDA in several important respects. First, although it was manufactured in the listed Pfizer facility in Ireland, it was packaged at a facility in Sao Paulo, Brazil, instead of one of the NDA-approved facilities in Frieburg, Germany or Vega Baja, Puerto Rico. Secondly, it was packaged in boxes containing thirty tablets, housed on three blister sheets of ten tablets each, and labeled, not in English, but in Portuguese. Lastly, the seized lots of Lipitor were manufactured in January 2003 and February 2003, and bore expiration dates of January 2006 and February 2006, respectively--three years after the manufacture date, as opposed to the two-year period required by the NDA.

Genendo believes these deviations from the requirements in the FDA-approved NDA are excused by 21 U.S.C. § 353(a) and its implementing regulation, 21 C.F.R. § 201.150. Genendo claims § 353(a) establishes an exemption from all labeling and packaging requirements in the FDCA, including the NDA requirements, so long as a drug is en route to or being held at an authorized drug repackager. Section 353(a), titled in part "Exemptions and consideration for certain drugs," provides as follows:

> (a) Regulations for goods to be processed, labeled, or repacked elsewhere
>
> The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

21 U.S.C. § 353(a).

The regulation promulgated is 21 C.F.R. § 201.150, which provides in pertinent part that a drug that will be repackaged "shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501(b) and 502(b), (d), (e), (f), and (g) of the act" if, among other things, there exists a written agreement--known as a § 201.150 agreement--that ensures the ultimate drugs will not be adulterated or misbranded. *See* 21 C.F.R. § 201.150(a)(2).

At the time it was seized, the imported Lipitor was destined for the Illinois corporation Phil & Kathy's, an FDA-registered repacker and labeler. Genendo had a written § 201.150 agreement with Phil & Kathy's for

the repacking and labeling of drugs for sale in the United States. Before trial, the government filed a seizure action for certain drugs held at Phil & Kathy's, and Phil & Kathy's entered into a consent decree resolving the government's claims against it. Although the government also contended in the district court that Genendo's § 201.150 agreement with Phil and Kathy's was inadequate, the court did not reach that issue.

Instead, the district court held a one-day trial, and ultimately ruled on the basis of the uncontested facts that by importing the Lipitor,[2] Genendo had introduced unapproved new drugs into interstate commerce in violation of 21 U.S.C. § 355(a). The court concluded that reading the exemption in § 353(a) as Genendo proposed would eviscerate the protections afforded by the new drug approval process. It thus attempted to harmonize the requirements of the new drug approval process and the § 353(a) exemption by reading the "labeling and packaging requirements" referred to in § 353(a) to apply to general "labeling and packaging, "but not the detailed requirements for packaging set forth in the NDA, which the court concluded were not affected by the exemption in § 353(a). The court also granted the government's request for condemnation of the drugs and injunctive relief.

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[2] The district court also concluded that the seized Zocor was an unauthorized new drug, but Genendo does not appeal that conclusion.

## II.

The sole issue on appeal is whether the seized Lipitor is an unapproved "new drug." *See* 21 U.S.C. § 355(a). Since Genendo admits that the seized Lipitor was not completely compliant with the NDA at the time it was seized, the only relevant question is whether, as Genendo maintains, § 353(a) exempts it from compliance with the NDA. This is a question of statutory interpretation subject to de novo review. *See Disability Rights Wis., Inc. v. Wis. Dep't of Pub. Instruction*, 463 F.3d 719, 724 (7th Cir. 2006). The FDA argues that the labeling and packaging requirements contained in the NDA are a critical piece of the new drug approval process and must be adhered to at all stages of the drug's production and distribution, and that § 353(a) does not change that. Genendo, however, contends that because the Lipitor was en route to an authorized repackager at the time it was seized, it is exempt from all labeling and packaging requirements, including all of those contained in the NDA.

As a threshold matter, we must determine the level of deference to be accorded the FDA's interpretation of § 353(a). As the agency that administers the statute, the FDA claims that its interpretation is entitled to *Chevron* deference. *See Chevron U.S.A., Inc. v. Natural Res. Def. Counsel, Inc.*, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984) (explaining deference due agency's interpretation of statute it administers). Genendo, however, claims that the unambiguous language of § 353(a)--directing the Secretary to promulgate regulations exempting certain drugs from "any labeling or packaging requirement of this

chapter"--compels the conclusion that the Lipitor is exempt from all labeling and packaging requirements--including those contained in the NDA. According to Genendo, any other interpretation flies in the face of the plain statutory language and is thus undeserving of our deference. In determining what level of deference to afford the FDA's interpretation, we ask first whether Congress has spoken to the precise question at issue. *Chevron*, 467 U.S. at 842-43. Genendo claims that it has done so in the form of § 353(a), and that the phrase "any labeling and packaging requirement" necessarily ends the matter.

But § 353(a) simply directs "the Secretary" to promulgate regulations exempting drugs en route to a repackager from labeling and packaging requirements; it does not itself provide for a complete exemption. *See Arner Co. v. United States*, 142 F.2d 730, 736 (1st Cir. 1944) ("Had Congress intended an outright exemption of bulk shipments from the labeling requirement without restrictive terms of any sort, there would have been no need for it to provide for regulations formulating the exemption; the law would have simply stated the exemption."). The problem with Genendo's argument is that it largely ignores the fact that the promulgated regulation, § 201.150, sets forth specific labeling and packaging requirements from which drugs being repackaged are exempt. The particular sections of the FDCA referenced in § 201.150 relate to the requirement that the package contain the name and address of the manufacturer or distributor, a statement of the quantity of the contents, the established name of the drug, active and inactive ingredients, and adequate warnings and directions for use. *See* 21 U.S.C. §§ 351(b), 352(b), (d), (e), (f), and (g).

Section 201.150 thus does *not* exempt drugs in transit to or at a repackager from *all* labeling and packaging requirements in the Act, as Genendo suggests--simply those listed.

Thus the statute is not so crystal clear as Genendo insists. Genendo's argument flows from an unstated belief that the word "any" in § 353(a) necessarily means "all." But that is not so. On the contrary, the first definition given for the word any is "one, a, an, or some." *Webster's Unabridged Dictionary of the English Language* 96 (2d ed. 2001). Although the statute could be read as if any meant all (the fourth possible definition given for the word "any"), it could also be read to give effect to the aforementioned definition of "any"--as directing the Secretary to promulgate regulations exempting drugs in transit to a repackager from *some* labeling and packaging requirements contained in the FDCA. *See First Bank & Trust v. Firstar Info. Servs., Corp.*, 276 F.3d 317, 325-26 (7th Cir. 2001) (rejecting argument that phrase "any services" in contract necessarily meant "all services" and concluding that phrase was ambiguous). Given that § 201.150 exempts drugs in transit only from specified labeling and packaging requirements, the Secretary apparently understood it to mean the latter.[3]

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[3] After argument, Genendo filed a letter of supplemental authority pursuant to Federal Rule of Appellate Procedure 28(j), calling the panel's attention to the recently decided Supreme Court case *Massachusetts v. E.P.A.*, 127 S. Ct. 1438, 167 L. Ed. 2d 248 (2007). In *Massachusetts*, the Court interpreted the phrase "any air pollutant" in the Clean Air Act to include carbon dioxide, reasoning in part that the use of the word "any" suggested that

Reading the statute in isolation, Genendo's interpretation may be a plausible one, but so too is the FDA's, particularly in light of the "'well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health.'" *United States v. Baxter Healthcare Corp.*, 901 F.2d 1401, 1408 (1990) (quoting *United States v. Article of Drug . . . Bacto-Unidisk. . .*, 394 U.S. 784, 798, 89 S. Ct. 1410, 22 L. Ed. 2d 726 (1969)). In short, there is enough ambiguity in the statute that we ask only whether the FDA's interpretation is based on a permissible construction

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the statute was intended to require regulation of *all* air pollutants. Genendo argues that *Massachusetts* stands for the proposition generally that the use of the word "any" in a statute necessarily means "all." *Massachusetts*, however, is not so broad. First, the Court's interpretation of the phrase "any air pollutant" was guided by the Clean Air Act's "sweeping definition of 'air pollutant,'" a definition that embraced "all airborne compounds of whatever stripe . . . through the *repeated* use of the word 'any.'" *Id.* at 1460 (emphasis added). The exemption in § 353(a) has no such "sweeping" language, nor does it contain anything else to convince us that the word "any" necessarily means "all." Nor does *Massachusetts* itself stand for such a proposition. Indeed, the Court cited with approval *Dep't of Hous. & Urban Dev. v. Rucker*, 535 U.S. 125, 122 S. Ct. 1230, 152 L. Ed. 2d 258 (2002), where it observed that the word "any" "has an expansive meaning, that is, *one or some*, indiscriminately of whatever kind." (emphasis added). *Massachusetts* interpreted a particular statute in an entirely different context, and concluded that in that case, "any" meant "all." The Court's holding does not in any way imply that in every case "any" means "all."

of the statute. *Chevron*, 467 U.S. at 843. Section 201.150's provision exempting drugs in transit from only certain labeling and packaging requirements is a permissible exercise of the authority delegated by the statute, and is consistent with the public health concerns animating the new drug approval process and the FDCA as a whole. *See id.* at 843, 866 (agency's interpretation comporting with purposes of underlying Clean Air Act Amendments is permissible given ambiguity in statute). Thus, unless the regulation (and the FDA's interpretation of it) is "arbitrary, capricious, or manifestly contrary to the statute," we will defer to it. *Id.* at 843-44.

We cannot say that the FDA's interpretation of the regulation and statute is "arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 843. Indeed, the FDA's interpretation makes good sense given that § 201.150 enumerates particular labeling and packaging requirements from which drugs in transit are exempt, and the NDA requirements are not among those enumerated. This understanding of the statute and regulation together is in keeping with our observation in *Baxter* that the new drug approval process "illustrates a congressional view that the way in which drugs are mixed and packaged is no less important than the chemical makeup of the drugs at issue," 901 F.2d at 1411. As the FDA points out, this precise packaging operation is subject to compromise if Genendo is given carte blanche to disregard the specifications in the NDA. Genendo maintains that the requirement in both § 353(a) and § 201.150 that the ultimate repackaged drugs cannot be adulterated or misbranded protects the consumer from any deviations from the NDA that occur before the drugs are

repackaged. But even assuming a flawless repackaging process at Phil & Kathy's pursuant to a satisfactory § 201.150 agreement (an assumption the government contests), certain deviations from the NDA's requirements are never rectified despite the repackaging. Notably, the fact that the Lipitor was packaged at an unapproved facility in Brazil can never be brought into compliance with the NDA (unlike the other deviations from the NDA such as the Portuguese labeling, improper expiration dates, and numbers of tablets in blister packs, which could theoretically be later rectified). It would be odd indeed for the FDA to go to such lengths to set up the process whereby facilities are approved for packaging new drugs, and yet allow drugs that will be repackaged to be packaged in an unapproved facility. If such a result were intended, we believe that the statute and accompanying regulation would say so explicitly.

Genendo's reliance on a Third Circuit case, *United States v. Kaybel*, 430 F.2d 1346 (3d Cir. 1970), does not convince us otherwise. In *Kaybel* the court overturned a wholesale drug distributor's conviction for introducing an unapproved new drug into interstate commerce. The court in *Kaybel* rejected the government's claim that the distributor needed to obtain approval of an additional new drug application before repacking a drug that complied in all respects with an already approved NDA from 500-unit bottles into 100-unit bottles. *Id.* at 1347. Not only does *Kaybel* not deal with the exemption provision in § 353(a), its application to Genendo's situation is further limited by the fact that the distributor in *Kaybel* was repackaging a drug that was *compliant in all respects* with the NDA, not attempting to remedy noncompliance

through re-packaging. In short, we think *Kaybel* is far less applicable than Genendo believes. Moreover, the primary rationale in *Kaybel*--that other mechanisms exist to prevent contamination of drugs by repackagers--does not extend to the situation where drugs are first packaged at an unapproved facility that lacks the FDA oversight of the packaging facilities listed in the NDA. *See In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 789-90 (8th Cir. 2006) (explaining importance of FDA oversight and FDCA labeling requirements in excluding "noncompliant and potentially unsafe pharmaceuticals").

The FDA's interpretation of § 353(a) and § 201.150 is entitled to deference, and it is neither arbitrary nor capricious. Although § 353(a) may have been interpreted as Genendo suggests, it is also open to the construction provided by the FDA, and that construction is entitled to deference under *Chevron* and is consistent with the language of § 201.150. It also comports with the underlying purposes of the FDCA, which exists to protect aspects of "the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection." *Arner*, 142 F.2d at 736; *see also Canadian Import*, 470 F.3d at 790 (labeling requirements are "manifestation of a congressional plan to create a 'closed system' designed to guarantee safe and effective drugs for consumers in the United States"). In sum, the exemption in § 353(a), as implemented by § 201.150, does not excuse compliance with an FDA-approved NDA, and thus the seized Lipitor, which Genendo concedes is noncompliant, is an unapproved new drug. *See* 21 U.S.C. § 355(a).

## III.

For the foregoing reasons, we affirm the judgment of the district court.

## APPENDIX C

**UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION**

**No. 03 C 6495**

**[Filed August 12, 2005]**

UNITED STATES OF AMERICA,
Plaintiff,

v.

1500 90-TABLET BOTTLES, more or less, of an article of drug . . . and all articles of drugs imported by Local Repack from Genendo Pharmaceutical N.V., . . .
Defendants-in-rem,

and

GENENDO PHARMACEUTICAL N.V., a Netherlands Antilles Corporation,
Defendant.

### MEMORANDUM OPINION AND ORDER

JAMES F. HOLDERMAN, District Judge:

This is an action by the government for the seizure and condemnation of certain prescription drugs and for a permanent inunction. This court has jurisdiction under 28 U.S.C. §§ 1331 and 1345, and under sections 332 and 334 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq (the "Act"). Defendant Genendo Pharmaceutical N.V. ("Genendo") has asserted certain affirmative defenses that the prescription drugs, which are the subject of this action, are exempt from seizure and condemnation pursuant to 21 U.S.C. § 353(a) and 21 C.F.R. § 201.150 and that the government's requested injunction therefore should not issue.

Genendo is a corporation headquartered in Curacao, Netherlands, Antilles. As a regular part of its business, Genendo purchases, trades and sells pharmaceuticals, including purchasing prescription drugs worldwide and importing them to the United States with the intention that they will be repackaged, relabeled and then distributed to consumers in the United States. Some of the drugs Genendo imports were originally intended for distribution outside of the United States. The prescription drugs that Genendo introduced or caused to be introduced into interstate commerce which are the subject of this action are: Lipitor ("Seized Lipitor"), which Genendo purchased in Brazil; and Zocor ("Imported Zocor"), which Genendo purchased in Argentina. Upon its entry into interstate commerce in the United States, the Imported Zocor, after FDA inspecting and photographing, was delivered to Phil & Kathy's, Inc., of Richton Park, Illinois ("Phil & Kathy's) pursuant to an agreement

between that company and Genendo.[1] Genendo had a written agreement with Phil & Kathy's regarding the repackaging and labeling of prescription drugs for human consumption ordered and paid for by Phil & Kathy's. The Seized Lipitor was seized by the government upon its entry into interstate commerce, and was held by the government. It was not delivered to Phil & Kathy's.

The government now seeks condemnation of the Seized Lipitor and a permanent injunction against Genendo. The government does not dispute that the Seized Lipitor and Imported Zocor each have the same chemical composition, as well as other similarities to the respective drugs Lipitor and Zocor, that are sold legally in the United States. The similarities to the other respective drugs sold as Lipitor and Zocor in the United States notwithstanding, the government argues that the Seized Lipitor and Imported Zocor are subject to condemnation as unapproved new drugs in violation of 21 U.S.C. § 355(a), and misbranded drugs in violation of 21 U.S.C. § 352. Genendo disagrees, and relies upon an exemption embodied in 21 U.S.C.

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[1] The Imported Zocor was seized by the government along with other drugs after reaching Phil & Kathy's. This action was originally commenced by the government only against Phil & Kathy's for seizure of certain articles of drugs. The government's complaint was later amended to include Genendo, and Genendo filed its Statement of Interest as to the Seized Lipitor (Dkt. No. 40). The government and certain principals of Phil & Kathy's entered into a consent decree resolving the claims of the government as to Phil & Kathy's. That consent decree was entered by this court on April 9, 2004. (Dkt. No. 53.)

§ 353(a) and 21 C.F.R. § 201.150 to argue that condemnation should not occur. Genendo waived its jury demand. A multi-day trial was set to begin on May 2, 2005, but due to the fine efforts and professionalism of counsel, the vast majority of the facts were agreed to and the remaining facts were presented to this court on the single day of May 2, 2005. For the following reasons, this court rules that Genendo by importing the Seized Lipitor and the Imported Zocor into the United States, introduced into interstate commerce unapproved new drugs in violation of 21 U.S.C. § 355(a). This court also grants the government's requested condemnation and injunctive relief as to Genendo's violations of 21 U.S.C. § 355.

## COURT'S FINDINGS OF FACT[2]

1. This action arises under the Constitution, laws, or treaties of the United States of America.

2. Plaintiff is the United States of America.

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[2] These facts are the uncontested facts as set forth in Attachment (a) of the Amended Pretrial Order. (Dkt. No. 155.) This court adopts these facts as its own. While evidence was presented to this court on May 2, 2005, none of that evidence is necessary to the disposition of this case. Accordingly, though a large part of Ms. Deborah Autor's testimony on May 2, 2005 was volunteered and impermissible opinion, this court rules as moot Genendo's pending Motion in Limine to Exclude the Trial Testimony of Deborah Autor.

3. This action is one for injunctive relief and seizure and condemnation under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("Act").

4. The *in rem* defendants are articles of drugs specifically, 60 boxes of Lipitor containing 10 mg tablets of Lipitor (lot 304-37521) in blister packs of ten tablets per blister sheet, 30 tablets per box, and 48 boxes containing 20 mg tablets of Lipitor (lot 304-37528) in blister packs often tablets per blister sheet, 30 per box, located in the northern judicial district of Illinois.

5. A substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of this action is situated in the northern judicial district of Illinois.

Statutory and Legal Background

6. The United States Food and Drug Administration ("FDA") is authorized to implement, administer, and enforce the Act. 21 U.S.C. § 393(d)(2); 21 U.S.C. § 371(a).

7. Defendant Genendo admits that a drug held for sale in interstate commerce that fails to meet the requirements of 21 U.S.C. § 352(c) and 21 C.F.R. § 201.15(c)(1) is deemed to be misbranded as a matter of law unless exempt by the Act.

8. Genendo admits that the packaging of a drug can be critical to its safety and effectiveness.

9. Genendo admits that 21 U.S.C. § 331(a) prohibits the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded."

10. Genendo admits that the Act prohibits distribution in interstate commerce of unapproved new drugs and that the definition of a "new drug" includes any drug, "the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . ." 21 U.S.C. § 321(p)(1).

11. Genendo admits that pursuant to the Act, a manufacturer must obtain FDA approval of a new drug application ("NDA") or an abbreviated new drug application ("ANDA") for each new drug before it may legally be introduced into interstate commerce pursuant to 21 U.S.C. § 355.

12. Genendo admits that an NDA must contain, among other things, information regarding the manufacturer and specification of the drug substance including the name and address of the facility at which it will be manufactured, the process and controls used during manufacturing and packaging, the strength and dosage form of the drug, the specifications related to the drugs' containers and closure systems, and the labeling for the product.

13. Genendo admits that the Act requires that the methods used in, and the facilities and controls

used for, the manufacture, processing, packaging, and holding of drugs conform to and be operated and administered in conformity with, current good manufacturing practice ("CGMP").

14. Genendo admits that 21 U.S.C. § 351(a)(2)(B) provides that a drug shall be deemed adulterated "if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of [the Act] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." Genendo further admits that the failure to comply with CGMP adulterates a drug as a matter of law.

15. 21 U.S.C. § 353(a) states, in pertinent part:

> The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repackaged in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

16. The FDA has issued Compliance Policy Guides ("CPG") and other guidance documents relating to, among other things, repacking and labeling of drugs.

Genendo's Activities

17. Genendo is a corporation headquartered in Curacao, Netherlands, Antilles. Genendo, as a regular part of its business either individually or through affiliates, purchases, trades and sells pharmaceuticals.

18. Genendo is not licensed as a drug wholesaler in any state in the United States.

19. Genendo's importation of drugs into the United States has occurred in interstate commerce.

20. Genendo admits that it caused to be imported pharmaceuticals to Phil & Kathy's, on two occasions not related to the *in rem* action involving the Seized Lipitor.

21. Genendo admits that at least some of the prescription drugs that Genendo imported into the United States in 2003 were originally intended for foreign distribution.

22. Genendo admits that some of the drugs that it caused to be imported to Phil & Kathy's Inc., were not labeled in English.

23. Genendo introduced or caused to be introduced the Seized Lipitor in interstate commerce intending to repackage and relabel it.

24. Genendo's prescription drug importation activities are subject to the Act and any exemptions that may be available under the Act and its implementing regulations.

25. The Seized Lipitor bears foreign-language labeling (*i.e.*, Portuguese labeling).

The Seized Lipitor

26. On August 20, 2003, Genendo filed an action for Declaratory Judgment that imports such as the Seized Lipitor were permitted under the Act.

27. The United States moved to dismiss the declaratory judgment action on jurisdictional grounds; specifically, there was no case or controversy because there was no agency action ripe for review.

28. On December 23, 2003, Judge Andersen granted the United States's motion to dismiss.

29. In September, 2003, Genendo advised the United States that it intended to import a shipment of Lipitor.

30. Genendo imported the Lipitor pursuant to an invoice dated September 17, 2003.

31. In an October 24, 2003 letter to the United States Attorney's Office, Genendo advised the United States that it intended to ship the Lipitor imported pursuant to the September 17, 2003, invoice, to be repackaged and labeled and then distributed and dispensed.

32. On or about December 16, 2003, the United States seized the Lipitor that Genendo had imported pursuant to the September 17, 2003, invoice.

33. The Seized Lipitor falls within the meaning of 21 U.S.C. § 321(g), (*i.e.*, articles of drugs).

34. Lipitor is a "new drug" under 21 U.S.C. § 321(p) of the Act.

35. Pfizer, Inc. ("Pfizer") manufactures Lipitor.

36. Pfizer submitted an NDA for Lipitor to the FDA for approval.

37. FDA assigned the number 20-702 to the Lipitor NDA.

38. FDA approved the NDA for Lipitor submitted by Pfizer.

39. A Pfizer facility located in Loughbeg, Ireland, is identified in the FDA-approved NDA for Lipitor as a manufacturing facility for Lipitor intended for sale and distribution in the United States, including 10 mg and Lipitor 20 mg dosage strengths.

40. FDA has conducted inspections of the Pfizer Loughbeg, Ireland facility that is identified in the approved NDA for Lipitor.

41. In the absence of an exemption, the only labeling that FDA has approved for Lipitor intended for sale in distribution in the United States is English-language labeling.

42. The expiration period in the FDA-approved NDA for Lipitor in blister packages intended for sale or distribution in the United States is two years from the date of manufacture.

43. Genendo purchased the Seized Lipitor in Brazil.

44. Genendo imported the Seized Lipitor into the United States.

45. Lot numbers are used to identify and track a specific batch of a drug.

46. The Lot numbers associated with the Seized Lipitor are:

1. Lot 304-37521 (10 mg); and

2. Lot 304-37528 (20 mg).

47. The Lot numbers are printed on the boxes in which the Seized Lipitor are packaged.

48. The manufacture dates for each lot of the Seized Lipitor are:

1. Lot 304.37521 - January 16, 2003; and

2. Lot 304-37528 - February 18, 2003.

49. Pfizer shipped the tablets that became the Seized Lipitor from Ireland in bulk containers.

50. The labeling on the Seizer Lipitor is in Portuguese; specifically, each "blister" sheet of 10 tablets and each 30 tablet box bears Portuguese labeling.

51. The package inserts in the boxes of Seized Lipitor are in Portuguese.

52. The Seized Lipitor, which Genendo imported on or about September 30, 2003 bears expiration dates of January 2006 (10 mg, lot 304-37521) and February 2006 (20 mg, lot 304-37528).

53. The Seized Lipitor bears expiration dates more than two years after the date of manufacture.

54. Plaintiff has not conducted any testing on the chemical composition of the Seized Lipitor and accordingly made no allegations in the Complaint that the chemical composition of the Seized Lipitor differs from that of a similar dosage of Lipitor that Pfizer sells in the United States.

55. The FDA-approved NDA for Lipitor lists Lipitor that is destined for sale in the United States to be packed in 100-tablet boxes containing 10 blister cards for 10 tablets.

56. The FDA-approved NDA for Lipitor does not list as packaging for Lipitor that is destined for sale in the United States 30-tablet boxes containing 3 blister cards of 10 tablets.

57. On December 16, 2003, the date of the seizure, the expiration period for the Seized Lipitor had not run.

58. January 16, 2005, was two years from the date of manufacture of the 10 mg Seized Lipitor (lot 304-27521), and February 18, 2005, was two years from the date of manufacture of the 20 mg Seized Lipitor (lot 304-37528). Blister-packed Lipitor that is intended for sale or distribution in the United States is subject to a two-year expiration period.

Imported Zocor

59. The 24,990 tablets of Zocor that are at issue in this case ("Imported Zocor") were manufactured by Merck & Co., Inc. ("Merck").

60. Genendo placed a purchase order for the Imported Zocor in Argentina and the Zocor was shipped from Argentina.

61. The Imported Zocor came from Merck lots A2411M1, A1954L1, A1953L1, A1661L1, and A1954L2.

62. The Imported Zocor is of 40 mg dosage strength.

63. The labeling on the Imported Zocor was in Spanish.

64. The package inserts for the Imported Zocor were in Spanish.

65. Zocor is a "new drug" under 21 U.S.C. § 321(p) of the Act.

66. Merck submitted an NDA for Zocor to FDA for approval.

67. FDA assigned the number 19-766 to the NDA for approval.

68. FDA approved Merck's NDA for Zocor.

69. The FDA-approved NDA for Zocor identifies only Merck facilities located in Caguas and Arecibo, Puerto Rico, as the drug product manufacturing establishments for 40 mg dosage strength Zocor intended for sale or distribution in the United States.

70. The FDA-approved NDA for Zocor identifies the Merck facility in Cramlington, United Kingdom, as a drug product manufacturing establishment only for 80 mg Zocor.

71. The FDA-approved NDA for Zocor identifies only the Merck facilities located in Caguas, Puerto Rico and Wilson, North Carolina as packaging establishments for Zocor intended for sale or distribution in the United States.

72. The only labeling identified in the FDA-approved NDA for Zocor intended for distribution in the United States is in English.

73. The FDA took photographs of the Imported Zocor prior to its delivery to Phil & Kathy's.

The Agreement with Phil & Kathy's

74. Phil & Kathy's, is an Illinois corporation located in Richton Park, Illinois.

75. Genendo, for some period of time, had a written agreement with Phil & Kathy's, regarding the repackaging and labeling of prescription human drugs ordered and paid for by Phil & Kathy's.

76. Genendo has never had an agreement with any entity other than Phil & Kathy's regarding repackaging and labeling of prescription drugs.

77. Joint Exhibit 12 is the Agreement between Phil & Kathy's and Genendo.

78. Prior to amending the complaint in this action to add Genendo as a defendant, and to seek an injunction against Phil & Kathy's and certain of its principals, the United States filed a seizure action against certain articles of drug located at Phil & Kathy's in Richton Park, Illinois. The United States and certain principals of Phil & Kathy's entered into a consent decree resolving the United States' claims. The court entered this consent decree on April 8, 2004.

79. 21 C.F.R. § 201.150 was promulgated pursuant to 21 U.S.C. § 353(a).

Likelihood of Recurrence

80. Genendo denies that a drug that does not meet all the requirements of the FDA-approved NDA,

including the approved labeling, is an unapproved new drug.

Supplemental Uncontested Facts[3]

Seized Lipitor

81. The Seized Lipitor was manufactured (*i.e.*, formed into tablets) by Pfizer, in Loughbeg, Ireland.

82. www.pfizer.ie includes links to pages stating that Lipitor is manufactured at the Loughbeg Drug Product Plant in Loughbeg, Ireland.

83. Pfizer shipped the tablets that, when packaged, became the Seized Lipitor, in bulk containers to Laboratorios Pfizer Ltda., Guarulhos - SP, Brazil.

84. The Seized Lipitor was packaged in "blister" packs and then in boxes of 30 tablets (3 blister sheets of 10 tablets each) at Laboratorios Pfizer Ltda., Guarulhos - Sao Paulo - SP, Brazil.

85. The only Pfizer manufacturing facilities identified in the FDA-approved NDA for Lipitor are those located in Loughbeg, Ireland, and Vega Baja, Puerto Rico.

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[3] These facts have been designated as "Supplemental" because they were agreed to after the pretrial conference on April 27, 2005, and were then added to the uncontested facts through the parties' Agreed Motion to Amend Attachments A, B, C, and E of the Final Pre-Trial Order (Dkt. No. 155.)

86. The only Pfizer packaging facilities identified in the FDA-approved NDA for Lipitor are those located in Freiburg, Germany and Vega Baja, Puerto Rico.

87. The FDA-approved NDA for Lipitor does not identify any packaging facility in Brazil for Lipitor.

88. The only labeling listed on the FDA-approved NDA for Lipitor is English-language labeling.

89. The expiration period in the FDA-approved NDA for Lipitor in blister packages in the United States is two years from the date of manufacture.

90. FDA has never inspected any Brazilian facility with respect to the packaging of Lipitor.

91. The Brazilian facility where the Seized Lipitor was packaged is not a registered facility pursuant to 21 U.S.C. § 360i with respect to 10mg and 20mg Lipitor.

92. Plaintiff has not conducted any testing of the Seized Lipitor.

93. The United States does not contend the Seized Lipitor is counterfeit within the meaning of the Act.

94. The expiration period for the Seized Lipitor began to run on the day manufacturing was complete.

Imported Zocor

95. In April 2003 Genendo caused to be introduced into interstate commerce 24, 990 tablets of 40 mg Zocor.

96. Genendo caused the Imported Zocor to be imported pursuant an agreement with International Pharmaceutical Exchange ("IPE").

97. Genendo purchased the Imported Zocor in Argentina.

98. The tablets in Zocor lots A2411M1, A1954L1, A1953L1, A1661L1, and A1954L2 were manufactured (granulated, pressed, formed and coated) by Merck (Merck Sharp & Dohme) in Argentina.

99. The tablets in Zocor lots A2411M1, A1954L1, A1953L1, A1661L1, and A1954L2 were packaged in blister packages and then in 30-tablet boxes by Merck (Merck Sharp & Dohme) in Argentina.

100. FDA has never inspected any Argentinian facility with respect to the manufacturing or packaging of Zocor.

101. The FDA-approved NDA for Zocor does not identify any manufacturing or packaging facilities in Argentina for Zocor.

102. The Imported Zocor was delivered to Phil & Kathy's.

The Agreement with Phil & Kathy's

103. In certain circumstances registered firms may repack and label drug products in compliance with the Act and associated regulations.

104. Genendo's intended destination for the Seized Lipitor, prior to the seizure of the Seized Lipitor, was a company called Phil & Kathy's.

105. Genendo introduced the Seized Lipitor in interstate commerce for repacking and relabeling by Phil & Kathy's.

106. Phil & Kathy's d/b/a Local Repack as a repacker and labeler is registered with the PDA as a repacker and labeler and is inspected by the PDA.

107. Registered repackers and labelers routinely repackage and label oral dosage forms of prescription drugs.

108. The Seized Lipitor and Imported Zocor are oral dosage forms of prescription drugs.

Likelihood of Recurrence

109. But for this lawsuit, Genendo would today be importing into the United States solid oral dosage forms of prescription human drugs that do not comply in all respects with FDA-approved NDAs.

## LEGAL ANALYSIS AND CONCLUSIONS

The government puts forth two bases for condemnation: (1) the Imported Zocor and Seized Lipitor are unapproved new drugs prohibited by 21 U.S.C. §§ 355(a), 331(d); and (2) the Imported Zocor and Seized Lipitor are misbranded drugs prohibited by 21 U.S.C. §§ 352(c), 331(a). Genendo responds that pursuant to the exemption embodied in 21 U.S.C. § 353(a) and 21 C.F.R. § 201.150 ("§ 353(a) exemption"), the Seized Lipitor is not an unapproved new drug, and that neither the Imported Zocor nor the Seized Lipitor are misbranded. The core dispute in this case is the government's first argument: whether the § 353(a) exemption excuses full compliance with the requirements of the FDA-approved New Drug Application ("NDA") for the respective drugs. As explained below, this court rules that the § 353(a) exemption does not excuse compliance with an FDA-approved NDA's requirements. Thus, as relevant to this case, a new drug's failure to be manufactured and/or packaged according to the exact requirements of an FDA- approved NDA are not exempted by § 353(a) of the Act.

A "new drug" is any drug, "the composition of which is such that such drug is not generally recognized among experts . . . as safe and effective for use . . . ." 21 U.S.C. § 321(p)(1). It is undisputed that the Seized Lipitor and Imported Zocor are both new drugs for purposes of the Act. (Facts ¶¶ 34, 65.) The Act prohibits the introduction of a new drug into interstate commerce unless that new drug is the subject of an

FDA-approved NDA. 21 U.S.C. § 355(a), 331(d).[4] In other words, if a party wishes to introduce into interstate commerce a "new drug," such as the Seized Lipitor and Imported Zocor, that party must first "file with the Secretary" an NDA. 21 U.S.C. § 355(b)(1). That NDA must contain certain information, including: "(A) full reports of investigations which have been made to show whether or not such drug is safe . . .; (B) a full list of the articles used as components of such drug; (C) a full statement of the manufacture, processing, and packaging of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug; (E) . . . samples of such drug... ; [and] (F) specimens of the labeling proposed to be used for such drug." 21 U.S.C. § 355(b)(1). Consistent with § 355(b)(1)(C), the FDA requires that an NDA include

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[4] 21 U.S.C. § 355(a) states:

> (a) Necessity of effective approval application
>
> No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

21 U.S.C. § 331 states in relevant part:

> The following acts and the causing thereof are prohibited:
>
> (a)...
>
> (d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 355, or 360bbb-3 of this title.

detailed information as to the exact facilities that manufacture and process the new drug. 21 C.F.R. § 314.50(d). Upon receipt of an NDA, the FDA reviews it and decides whether or not to approve the NDA. 21 U.S.C. § 355(b)(1). If the FDA does not approve the NDA for the proposed new drug, then that drug is an unapproved new drug that cannot be introduced into interstate commerce. 21 U.S.C. § 355(a).

Both Lipitor and Zocor are sold legally in the United States pursuant to FDA-approved NDAs. The Seized Lipitor and the Imported Zocor, however, do not comply in all respects with the FDA-approved NDAs for the respective drugs. Pfizer Inc. ("Pfizer") manufactures Lipitor and it is legally sold in the United States pursuant to an FDA-approved NDA. (Facts ¶¶ 35-38.) The only Pfizer manufacturing facilities identified in the FDA-approved NDA for Lipitor are those located in Loughbeg, Ireland, and Vega Baja, Puerto Rico. (*Id.* ¶ 85.) The Seized Lipitor was manufactured in Loughbeg, Ireland. (*Id.* ¶ 81.) The only Pfizer packaging facilities identified in the FDA-approved NDA for Lipitor are those located in Freiburg, Germany and Vega Baja, Puerto Rico. (*Id.* ¶ 86.) The Seized Lipitor was not packaged in either of these facilities, it was packaged at Laboratorios Pfizer Ltda., Guarulhos - Sao Paulo - SP, Brazil. (*Id.* ¶ 84.) The FDA-approved NDA for Lipitor does not identify any packaging facility in Brazil for Lipitor. (*Id.* ¶ 87.) The only labeling listed on the FDA-approved NDA for Lipitor is English-language labeling. (*Id.* ¶ 8.) The Seized Lipitor was not labeled in English, it was labeled in Portugese. (*Id.* ¶ 50-51.)

Merck & Co., Inc. ("Merck") manufactures Zocor and it is legally sold in the United States pursuant to an FDA-approved NDA. (*Id.* ¶¶ 59, 61.) The FDA-approved NDA for Zocor identifies only Merck facilities located in Caguas and Arecibo, Puerto Rico, as the manufacturing facilities for the 40 mg dosage strength Zocor intended for sale in the United States. (*Id.* ¶ 69.) The Imported Zocor is of 40 mg dosage strength. (*Id.* ¶ 62.) The Imported Zocor was manufactured by Merck in Argentina. (*Id.* Supp. ¶¶ 98, 99.) The FDA-approved NDA for Zocor does not identify any manufacturing or packaging facilities in Argentina for Zocor. (*Id.* ¶ 101.) The only labeling identified in the FDA-approved NDA for Zocor intended for distribution in the United States is English. (*Id.* ¶ 72.) The labeling on the Imported Zocor was not in English, but in Spanish. (*Id.* ¶ 63.)

The failure of the Seized Lipitor and the Imported Zocor to comply with the requirements of the FDA-approved NDAs means that those drugs cannot be introduced into interstate commerce under the cover of the respective FDA-approved NDAs. An FDA-approved NDA is in effect an approved "recipe" for making a drug. *See United States v. Baxter Healthcare Corp.*, 901 F.2d 1401, 1412 (7th Cir. 1990). That recipe includes not only the chemical composition of the drug, but also the procedure used in creating the drug. As the Seventh Circuit stated, the detailed requirements of the new drug approval process of § 355 reflect "a Congressional view that the way in which drugs are mixed and packaged is no less important than the chemical makeup of the drugs." *Id.* at 1411. Therefore, it is not enough that the Imported Zocor and Seized Lipitor share the same chemical makeup of FDA-approved Zocor and Lipitor sold in the United States.

To be introduced into interstate commerce under the cover of an FDA-approved NDA, the drugs must comply with all requirements of that NDA. *Id.* The drugs at issue here do not. The Imported Zocor was manufactured at a facility not listed on the FDA-approved NDA for Zocor. The Seized Lipitor was packaged at a facility not listed on the FDA-approved NDA for Lipitor. Accordingly, the FDA has not approved the conditions under which the Imported Zocor was manufactured, and, similarly, the FDA has not approved the conditions under which the Seized Lipitor was packaged. The failure to comply with the requirements of the FDA-approved NDAs means that the Imported Zocor and Seized Lipitor cannot be introduced into interstate commerce pursuant to the FDA-approved NDAs for Zocor and Lipitor. The result is that the Imported Zocor and Seized Lipitor are unapproved new drugs that cannot lawfully be introduced into interstate commerce. 21 U.S.C. § 355(a), 331(d).

Genendo concedes, as it must, that the Imported Zocor is an unapproved new drug because it was manufactured at a location not listed on the FDA-approved NDA.[5] As to the Seized Lipitor, however, Genendo argues that its failure to comply with the FDA-approved NDA's packaging requirement is excused by the § 353(a) exemption, and, that if the Seized Lipitor had been allowed to be repackaged at a

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[5] As stated in its Closing Argument, "Genendo does not contend that the imported drugs need not be manufactured, as opposed to packaged or labeled, in a facility listed on the NDA . . ." (Dkt. No. 172, at 14 n. 10.)

facility (regardless of whether that facility is listed on the relevant FDA-approved NDA) "it would have been in complete compliance with the Act." (Dkt. No. 172 at 22.) This court disagrees. The § 353(a) exemption states, in relevant part:

> The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed . . . .

21 U.S.C. § 353(a). The PDA promulgated 21 C.F.R. § 201.150 in response to the § 353 exemption. According to Genendo, the FDA must recognize the Seized Lipitor as exempted from the FDA-approved NDA's "packaging requirement," because the Seized Lipitor will be "repacked" at an establishment "other than [that] where originally . . . packed" pursuant to the § 353(a) exemption. 21 U.S.C. § 353(a).

It is clear, as the government argues, that to accept Genendo's argument regarding the § 353(a) exemption would necessarily lead to the evisceration of the protections afforded by the new drug approval process. The Seized Lipitor was not packaged at a facility listed on the FDA-approved NDA, and Genendo has no intention of having the Seized Lipitor, or any other similar drug that it might import, packaged at facilities listed on the relevant FDA-approved NDA. Genendo's position is that because of the § 353(a) exemption, the labeling and packaging requirements

of the FDA-approved NDA are "irrelevant." (Dkt. No. 172 at 21.) In support, Genendo argues that to rule otherwise would eviscerate the § 353(a) exemption. Thus, the issue this court is presented with, as Genendo frames it, is to either side with the government, thereby eviscerating the § 353(a) exemption, or to side with Genendo, thereby eviscerating the new drug approval process.

If compelled to choose, this court would eviscerate the § 353(a) exemption and leave the new drug approval process unscathed. As the Supreme Court has recognized, the Act "touches phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection," *United States v. Dotterweich,* 320 U.S. 277, 280, 64 S. Ct. 134, 88 L. Ed. 48 (1943), and as such it is a "well-accepted principle that [the Act] is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." *Baxter,* 901 F.2d at 1408 (quoting *United States v. An Article of Drug . . . Bacto-Unidisk . . .,* 394 U.S. 784, 798, 89 S.Ct. 1410, 1418, 22 L.Ed.2d 726 (1969)). Maintaining the panoply of the new drug approval process at the expense of the § 353(a) exemption is more consistent with protecting the public health than avoiding interfering with certain commercial activity at the expense of the new drug approval process. Therefore, if necessary, the § 353(a) exemption must give way to the new drug approval process.

This court, however, has an "obligation to construe the two statutory provisions at issue in this case in such a way as to avoid conflicts between them, if such a construction is possible and reasonable." *Precision*

*Indus., Inc. v. Qualitech Steel SBQ, LLC*, 327 F.3d 537, 544 (7th Cir. 2003). As the Supreme Court observed, and the Seventh Circuit reiterated:

> We 'are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.' *Morton v. Mancari*, 417 U.S. 535, 551, 94 S.Ct. 2474, 2483, 41 L.Ed.2d 290 (1974). We should read federal statutes 'to give effect to each if we can do so while preserving their sense and purpose.' *Watt v. Alaska*, 451 U.S. 259, 267, 101 S.Ct. 1673, 1678, 68 L. Ed. 2d 80 (1981); see also *United States v. Fausto*, 484 U.S. 439, 453, 108 S.Ct. 668, 676-77, 98 L.Ed.2d 830 (1988).

*Precision Indus., Inc.*, 327 F.3d at 544 (citations omitted). The new drug approval process embodied in § 355 and the § 353(a) exemption can be construed in a way "to give effect to each . . . while preserving their sense and purpose." *Id.* This requires distinguishing between general "labeling" and "packaging" requirements and the "labeling" and "packaging" requirements of an FDA-approved NDA. The former are regulated in various ways by the Act, 21 U.S.C. § 352, but the latter are given special treatment under the Act in that they are ingredients of an FDA-approved recipe as provided for in § 355. As the government correctly argues, the "packaging" and "labeling" ingredient of an FDA-approved NDA includes more than just a type of packaging with descriptive terms. It also includes the "methods used

in, and the facilities and controls used for, the . . . processing and packing of such drug." 21 U.S.C. § 355(b)(1)(D). Thus, according to the plain language of the statute, the packaging of a new drug does not just refer to the material that encases a drug, but also includes the method by which the drug is packaged and the facility where the drug is packaged. Genendo, through its repacker, may be able to replicate the type of packaging material, but it cannot replicate the combination of the FDA-approved facility and method for packaging as to a specific drug.

Nothing in the plain language of the exemption, or in the legislative history provided to the court by the parties, suggests any intent on the part of Congress to allow any drug importer to make changes to the FDA-approved NDA for a drug.[6] In fact, the Act has detailed provisions for approving changes to an already approved NDA. 21 U.S.C. § 356a; 21 C.F.R. § 314.70. In other words, nothing in the § 353(a) exemption suggests an intent to exempt changes in the FDA-approved recipe for a new drug, and this court will not construe the statutory provisions to allow Genendo to make such changes. *Spokane & Inland Empire RR Co. v. United States,* 241 U.S. 344, 350, 36 S. Ct. 668, 60 L.

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[6] The First Circuit has explained that the purpose of the § 353(a) exemption was to "avoid unwarranted interferences with certain legitimate commercial operations, such as the canning of food at branch canneries and delivery to a central plant for labeling, or the bulk shipment of crude drugs for processing and repacking before distribution to consumers." *Arner Co. v. United States,* 142 F.2d 730, 734 n.3 (1st Cir. 1944) (*citing* Sen. Rep. No. 493, 73rd Cong., 2d Sess., 1934).

Ed. 1037 (1916) ("[e]xceptions from a general policy which a law embodies should be strictly construed; that is, should be interpreted as not to destroy the remedial process intended to be accomplished by the enactment.") Reading the § 353(a) exemption to apply to "labeling" and "packaging" requirements, but not to the detailed requirements of an FDA-approved NDA, which admittedly include labeling and packaging requirements, gives the exemption effect without intruding on the new drug approval process.

This conclusion is not affected by *United States v. Kaybel,* 430 F.2d 1346 (3d Cir. 1970) as Genendo argues. In *Kaybel,* the defendants were charged with criminal violations of the Act for introducing into interstate commerce unapproved new drugs, or, in other words, the defendants were charged with distributing new drugs for which no FDA-approved NDA was effective. *Id.* at 1347. Specifically, the defendants were distributing into interstate commerce Enovid 5 mg. *Id.* As the Third Circuit explained, that Enovid 5 mg. was sold legally in the United States pursuant to an FDA-approved NDA:

> Before placing [the Enovid 5mg.] on the market, [the original manufacturer] filed a new drug application with the Food and Drug Administration as required by the Food, Drug, and Cosmetic Act. 21 U.S.C. § 355. The application was approved and became effective on March 9, 1961. While this approval was in effect, [the defendants] *repackaged* Enovid 5 mg. tablets *from the manufacturer's original 500-unit bottles* into its own 100-unit bottles,

> and sold the repackaged drug in interstate commerce.

*Id.* at 1347. What is important to note from this excerpt is that the defendants in *Kaybel* were repackaging drugs that were compliant with an FDA-approved NDA. The Third Circuit eventually held that the repackaging of drugs that were compliant with an FDA-approved NDA did not violate § 355. But in this case, the Seized Lipitor was not compliant with an FDA-approved NDA, and Genendo has no intention of making the Seized Lipitor compliant because Genendo did not intend to have the drug packaged or repackaged at a facility listed on the FDA-approved NDA for Lipitor. Thus, *Kaybel* is distinguishable from this case. And even if *Kaybel* supported the proposition that a new drug need not be packaged according to the requirements of an FDA-approved NDA, this court believes that view would be inconsistent with that espoused by the Seventh Circuit. *Baxter,* 901 F.2d at 1412 (explaining that § 355 "reflects a Congressional view that the way in which drugs are mixed and packaged is no less important than the chemical makeup of the drugs).

Accordingly, as to the Seized Lipitor, this court rules that it is subject to condemnation as an unapproved new drug.[7] 21 U.S.C. §§ 334, 355(a). The Seized Lipitor is a new drug. It is not the subject of an FDA-approved NDA because it does not comply with

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[7] The court rules, even though Genendo has already conceded it, that the Imported Zocor is also an unapproved new drug. 21 U.S.C. §§ 355(a), 331(d).

all the requirements of the relevant FDA-approved NDA. Finally, its lack of compliance with an FDA-approved NDA is not excused by § 353(a), because that statutory provision does not provide an exemption from the new drug approval requirements of § 355.

The government has also requested injunctive relief pursuant to § 332(a), which this court finds appropriate and necessary with regard to Genendo's activity of introducing into interstate commerce drugs prohibited by § 355. When the government seeks an injunction pursuant to a statute protecting the public health, the government need only show that the defendant has violated the statute and that there is some "cognizable danger of recurrent violations." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633, 73 S. Ct. 894, 97 L. Ed. 1303 (1953); *SEC v. Holschuh*, 694 F.2d 130, 144 (7th Cir. 1982). Genendo has at least twice introduced or caused to be introduced into interstate commerce drugs that violate § 355 of the Act. Such past misconduct is "highly suggestive of the likelihood of future violations." *CFTC v. Hunt*, 591 F.2d 1211, 1220 (7th Cir. 1979) (citation omitted). It is also significant that Genendo has continued to assert that its conduct does not violate the Act. *Id.* Finally, it is an uncontested fact, that "but for this lawsuit, Genendo would today be importing into the United States solid oral dosage forms of prescription human drugs that do not comply in all respects with FDA-approved NDAs." (Facts ¶ 109.) Given this admission from Genendo that absent legal action it will continue to import drugs that violate § 355, it is clear that injunctive relief is necessary to prohibit Genendo from

introducing into interstate commerce unapproved new drugs prohibited by § 355.[8]

## CONCLUSION

Accordingly, the Seized Lipitor is subject to condemnation, and, therefore, the government may proceed to condemn the Seized Lipitor under 21 U.S.C. § 334(a) because it is an unapproved new drug that has been introduced into interstate commerce as prohibited by § 355(a). Genendo violates 21 U.S.C. § 331(d) by introducing into interstate commerce and causing the introduction and delivery for introduction

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[8] The court's ruling makes it unnecessary to rule on the other issues presented by the parties. As Genendo's activities at issue here do not fall within the § 353(a) exemption, it is unnecessary to determine whether the agreement Genendo had with Phil & Kathy's satisfies the requirements of 21 C.F.R. § 201.150. Furthermore it is unnecessary for this court to determine the overlapping issue of whether the drugs in this case are also misbranded pursuant to 21 U.S.C. § 352(c). The injunction this court is issuing barring Genendo from introducing into drugs into interstate commerce that violate § 355 will prohibit the introduction of drugs like the Imported Zocor and Seized Lipitor. There are no facts in the record indicating that Genendo has or will violate § 352(c) without also violating § 355, and the uncontested facts establish only that Genendo, absent this lawsuit, intended to continue to import drugs that "don not comply in all respects with FDA-approved NDAs." (Facts ¶ 109.) This court has enjoined that activity. Therefore, any drugs Genendo imports must be NDA compliant, which means the drug's labeling must comply with the relevant FDA-approve NDA. 21 U.S.C. § 355(b)(1)(F).

into interstate commerce "new drugs" within the meaning of 21 U.S.C. § 321(p), which do not comply with the specifications of a New Drug Application approved by FDA that meets the requirements of 21 U.S.C. § 355(b) and (d). Defendant Genendo, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this order by personal service or otherwise are hereby permanently enjoined from introducing into interstate commerce unapproved new drugs in violation of 21 U.S.C. §§ 331(d); 355.

ENTER:

JAMES F. HOLDERMAN

United States District Court Judge

Date: August 12, 2005.

## JUDGMENT IN A CIVIL CASE

Decision by Court. This action came to trial before the Court. The issues have been tried and a decision has been rendered.

IT IS HEREBY ORDERED AND ADJUDGED that Permanent Injunction is granted in favor of plaintiff United States of America and against defendant Genendo Pharmaceutical N.V.

Date: 8/12/2005